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PATENT
ATTORNEY DOCKET NO. 00786/247003

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Christine M. Colbert

Printed name of person mailing correspondence

Christine M. Colbert
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Brian Seed et al.

Art Unit: 1648

Serial No.: 09/939,537

Examiner: Emily M. Le

Filed: August 24, 2001

Customer No.: 21559

Title: TARGETED CYTOLYSIS OF HIV-INFECTED CELLS BY
CHIMERIC CD4 RECEPTOR-BEARING CELLS

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APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C.

§ 154(b) mailed with the Notice of Allowance on October 31, 2003 in connection with the above-captioned patent application, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the current patent term adjustment should be 372 days (i.e., the period in excess of fourteen months from the filing date of the present patent application to the mailing date of the Notice of Allowance).

In support of this application, Applicants first summarize crucial dates and actions

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Repln. Ref: 02/07/2005 AKELLEY 0013241000
DAM:032095 Name/Number:09939537
FEE: 02/07/2005 \$400.00 C.R.

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that result in patent term adjustment. The present patent application was filed on August 24, 2001. A Notice to File Missing Parts was mailed on October 31, 2001 and Applicants mailed a complete reply to this Notice on December 10, 2001. Applicants' reply was received by the U.S. Patent and Trademark Office ("the U.S.P.T.O.") on January 16, 2002, as indicated by the U.S.P.T.O. stamp on the return postcard included with the reply (Exhibit 1). No action under 35 U.S.C. § 132 was mailed, and a Notice of Allowance was mailed on October 31, 2003, which is later than fourteen months after the filing date of the present patent application.

The rules governing patent term adjustment due to examination delay are provided for in 37 C.F.R. § 1.702, which states:

[T]he term of an original patent shall be adjusted if issuance of the patent was delayed due to the failure of the Office to:

(1) Mail at least one notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a).

37 C.F.R. § 1.703 states:

(a) The period of adjustment under 1.702(a) is the sum of the following periods:

(1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) ... and ending on the mailing date of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

With regard to reductions in patent term adjustment, 37 C.F.R. § 1.704(b) states:

[T]he period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning the day after the date that is three months after the mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed.

In addition, 37 C.F.R. § 1.703(f) states that the “date indicated on any certificate of mailing or transmission under § 1.8 shall not be taken into account” in calculating the period of patent term adjustment.

The period from the August 24, 2001 filing date of the application to the October 31, 2003 mailing date of the Notice of Allowance spans fourteen months and 372 days. Applicants submit that the patent term should be extended for the 372 days in excess of the fourteen-month time period provided for in 37 C.F.R. § 1.702. There were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination as set forth in 37 C.F.R. § 1.704.

Applicants’ calculation of the patent term adjustment period differs from that calculated by the Office, and Applicants submit that the Office’s calculation is in error. In particular, in reference to the Patent Term Adjustment History on the PAIR system (Exhibit 2), Applicants note that the period of patent term adjustment was reduced from a total of 372 days by 25 days. This reduction appears to be due to the number of days in excess of three months after the October 31, 2003 mailing date of the Notice to File

Missing Parts (Item 5; Exhibit 2) that the application was deemed to be complete (Item 12; Exhibit 2). Applicants note that they replied to the Notice to File Missing Parts on December 10, 2001 (Items 7-10; Exhibit 2) and that this reply was received by the U.S.P.T.O. on January 16, 2002, as indicated by the U.S.P.T.O. stamp on the return postcard included with the reply (Exhibit 1). Thus, the U.S.P.T.O. received Applicants' reply within three months of the mailing date of the Notice to File Missing Parts. Accordingly, the reply was timely filed under 37 C.F.R. § 1.704(b) and the period of patent term adjustment should not be reduced on this basis¹.

In addition, Applicants note that the present patent application is not subject to a Terminal Disclaimer.

In view of the above facts, this application is currently entitled to 372 days of patent term adjustment under 37 C.F.R. § 1.703.

¹ Applicants note that the PAIR system date for when the present application was deemed to be complete reflects a delay in processing Applicants' reply to the Notice to File Missing Parts that could be due to the special mail handling and decontamination procedures instituted after the September 11, 2001 attack.

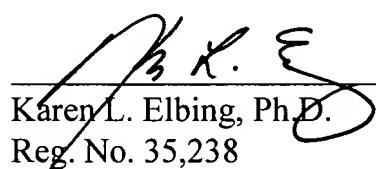
CONCLUSION

Applicants submit that the current patent term adjustment should be 372 days and request reconsideration of the patent term adjustment.

Enclosed is a check in the amount of \$400.00 for the fee set forth in 37 C.F.R. § 1.18(f). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 17 December 2003


Karen L. Elbing, Ph.D.
Reg. No. 35,238

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101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
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Alexandria, VA 22313-1450

REPLY TO NOTICE OF ALLOWANCE AND NOTICE OF ALLOWABILITY

In reply to the Notice of Allowance and Notice of Allowability that were mailed in connection with the above-captioned case on October 31, 2003 and having confirmation number 3555, enclosed are:

- A completed fee transmittal form PTOL-85; and
- A check for \$1,660.00 to cover the issue fee required by 37 C.F.R. § 1.18(a) of \$1,330.00, the publication fee of \$300.00, and the patent copy fee required by 37 C.F.R. § 1.19(a)(1)(i) of \$30.00 for ten patent copies.

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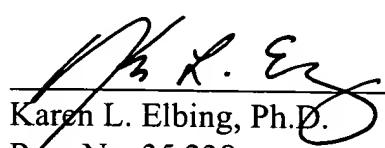
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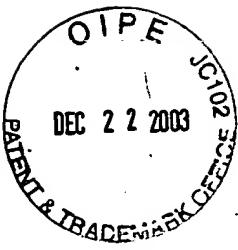
Respectfully submitted,

Date: 17 December 2003


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Facsimile: 617-428-7045

EXHIBIT 1



PROSECUTION

PATENT ATTORNEY DOCKET NUMBER: 00786/247003

Applicant/Patentee: Brian Seed et al
Serial/Patent Number: 09 / 939, 537
Filed/Issued: August 24, 2001

Title: TARGETED CYTOLYSIS OF HIV-INFECTED CELLS BY HOMOLOGOUS CD4

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<input checked="" type="checkbox"/> Transmittal Letter	Pages: <u>2</u>	<input type="checkbox"/> Declaration & POA	Pages: <u> </u>
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<input type="checkbox"/> Appeal Brief	Pages: <u> </u>	<input type="checkbox"/> Cited References	Pages: <u> </u>
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Patent Term Adjustment (PTA) for publication number: 09/939,537		
		Days
Filing or 371(c) Date:	08-24-2001	USPTO Delay (PTO): 372
Issue Date of Patent:	-	Three Years: -
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL): 25
Post-Issue Petitions (days):	+0	Total PTA: 347
USPTO Adjustment (days):	+0	Explanation of Calculations

Patent Term Adjustment History		
Number	Date	Contents Description
22	10-31-2003	Mail Notice of Allowance
21	10-31-2003	Notice of Allowance Data Verification Completed
20	10-24-2003	Notice of Allowability
17	06-20-2003	Case Docketed to Examiner in GAU
16	01-23-2002	Preliminary Amendment
15	01-23-2002	Information Disclosure Statement (IDS) Filed
14	03-23-2002	Case Docketed to Examiner in GAU

13	02-28-2002	Application Dispatched from OIPE	↑	↑	25
12	02-26-2002	Application Is Now Complete	↑	↑	
10	12-10-2001	A payment by the applicant to cover the cost of basic filing, claims, issue fees, etc.	↑	↑	
9	12-10-2001	A set of symbols and procedures, provided to the PTO on a set of computer listings, that describe in	↑	↑	
8	12-10-2001	A set of symbols and procedures, provided to the PTO on a set of 3 1/2 inch diskettes in computer read	↑	↑	
7	12-10-2001	Applicant has submitted new drawings to correct Corrected Papers problems	↑	↑	
6	02-11-2002	CRF Is Good Technically / Entered into Database	↑	↑	
5	11-01-2001	Incomplete Application under Rule 53(b) - Filing Date Assigned	↑	↑	
4	09-10-2001	Correspondence Address Change	↑	↑	
3	09-05-2001	IFW Scan & PACR Auto Security Review	↑	↑	
2	08-24-2001	CRF Disk Has Been Received by Preexam / Group / PCT	↑	↑	
1	08-24-2001	Initial Exam Team nn	↑	↑	

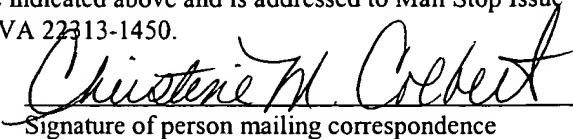


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Christine M. Colbert

Printed name of person mailing correspondence


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COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

In the Notice of Allowability that was mailed in connection with the above-captioned case on October 31, 2003 the Office states, under Reasons for Allowance:

The instant claimed invention is directed to a chimeric receptor that comprises an extracellular portion which includes a CD4 domain that specifically recognizes and binds HIV or an HIV-infected cell but which does not mediate HIV infection, a transmembrane portion that comprises the CD7 transmembrane domain, and an intracellular portion which signals a cell bearing said receptor to destroy a receptor-bound HIV of [sic, or] HIV-infected cell. The closest prior art does not teach or suggest a chimeric receptor that comprises a) an extracellular portion which includes a CD4

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domain that specifically recognizes and binds HIV or an HIV-infected cell but which does not mediate HIV infection, b) a transmembrane portion that comprises the CD7 transmembrane domain, and c) an intracellular portion which signals a cell bearing said receptor to destroy a receptor-bound HIV of [sic, or] HIV-infected cell.

Applicants wish to clarify the record with respect to this statement. Claims 22-30 have been allowed. Independent claim 22 (from which all other claims depend) is reproduced below:

22. A proteinaceous chimeric receptor, said receptor comprising (a) an extracellular portion which includes a CD4 domain that specifically recognizes and binds HIV or an HIV-infected cell but which does not mediate HIV infection, (b) a transmembrane portion, and (c) an intracellular portion which signals a cell bearing said receptor to destroy a receptor-bound HIV or HIV-infected cell.

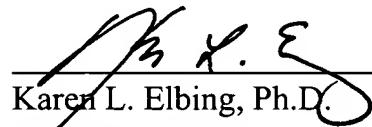
Applicants note that claim 22 does not require the transmembrane portion to include a CD7 transmembrane domain. In fact, only dependent claim 25 recites that the transmembrane portion contains a CD7 transmembrane portion.

Applicants assume, therefore, that the Office's statement is intended to convey the fact that CD7 is one possible transmembrane portion that may be used for the claimed chimeric receptors. If the Office disagrees with Applicants on this interpretation of the allowed claims, in particular, claim 22, prosecution in this case should be re-opened to allow resolution of this issue.

No fee is believed to be due in connection with these comments. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 17 December 2003


Karen L. Elbing, Ph.D.
Reg. No. 35,238

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail**

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CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

21559 7590 10/31/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110



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<i>Christine M. Colbert</i>	(Depositor's name)
<i>Christine M. Colbert</i>	(Signature)
December 17, 2003	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,537	08/24/2001	Brian Seed	00786/247003	3555

TITLE OF INVENTION: TARGETED CYTOLYSIS OF HIV-INFECTED CELLS BY CHIMERIC CD4 RECEPTOR-BEARING CELLS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional	NO	\$1330	\$300	\$1630	02/02/2004
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EXAMINER	ART UNIT	CLASS-SUBCLASS
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LE, EMILY M	1648	424-093210
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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

THE GENERAL HOSPITAL CORPORATION, INC. BOSTON, MA

Please check the appropriate assignee category or categories (will not be printed on the patent); individual corporation or other private group entity government

4a. The following fee(s) are enclosed:

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4b. Payment of Fee(s):

A check in the amount of the fee(s) is enclosed.
 Payment by credit card. Form PTO-2038 is attached.
 The Director is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number 03-2095 (enclose an extra copy of this form).

Director for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) <u>K. R. E.</u> (Date) <u>17 December 2003</u> <p>NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.</p> <p>This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.</p> <p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.</p>	12/24/2003 RMONDAF2 00000117 09939537 01 FC:1501 1330.00 0P 02 FC:1504 300.00 0P 03 FC:8001 30.00 0P RECEIVED DEC 24 2003
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